ATTORNEY DOCKET NO.: P-7322 CON

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Total Pages

UTILITY PATENT APPLICATION TRANSMITTAL

FIRST NAMED INVENTOR OR APPLICATION IDENTIFIER: MARKUS HALLER ET AL.
TITLE: IMPLANTABLE DRUG INFUSION DEVICE HAVING A FLOW REGULATOR

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Via Courier

Sir:

We are transmitting herewith the attached:

X **Patent Application Transmittal**

X **Specification:**
Total pages: 23 (including claims and abstract) :Spec. 14 sheets; Claims 8 sheets; Abstract 1 sheet

X **Drawings:**
Total sheets: 6
☐ formal X informal

Combined Declaration and Power of Attorney:
☐ newly executed
X copy from prior application
☐ Deletion of Inventor(s) - Signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
☐ Incorporation by Reference - *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.*

Accompanying application parts:
☐ Notification of filing a
X Assignment of the Invention to Medtronic, Inc.
☐ Information Disclosure Statement
X Information Disclosure Statement of prior application
X PTO Form 1449 of prior application
☐ Copies of IDS citations
X Preliminary Amendment
☐ A copy of the Petition or Conditional Petition for Extension of Time in the prior application.
X Return Postcard

IF A CONTINUING APPLICATION:

X **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP) of prior application No. 09/017,194.**

☐ **Amend the specification by inserting before the first line the sentence: This application is a ☐ continuation ☐ division ☐ continuation in part of application number__, filed _____.**

☐ **Cancel in this application original claims _____of the prior application before calculating the filing fee. (At least the original independent claim must be retained for filing purposes.)**

X **The prior application is assigned of record to Medtronic, Inc.**

X **The Power of Attorney in the prior application is to: Medtronic, Inc.**

☐ This application claims the benefit of U.S. Provisional Application(s) Serial No.(s) _____, filed _____.

☐ Address all future correspondence to:

Thomas F. Woods, Reg. No. 36,726
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FEE CALCULATION	No. of Claims Filed	Claims Included in Base Fee		No. of Extra Claims	Rate	Fee
Total Claims	03	20	=	0	x 18	$
Independent Claims	01	03	=	0	x 78	$
Multiple Dependent Claims					+ 270	
Basic Filing Fee						$710
					TOTAL	**$710**

X Charge Deposit Account No. 13-2546 the sum of $ 710.00 (Filing Fee) for a total of **$ 710.00.**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

11-10-00
Date

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Markus Haller et al. Examiner: L.Thanh

Serial No.: 09/017,194 Group Art Unit: 3763

Filed : February 2, 1998 Docket: P-7322 CON

Title : IMPLANTABLE DRUG INFUSION DEVICE HAVING A FLOW REGULATOR

PRELIMINARY AMENDMENT

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Via Courier

Dear Sir:

Please preliminarily amend the above-identified application as follows:

IN THE DRAWINGS

Please amend figures 5A, 5B and 5C as shown in the amended drawing thereof set forth in exhibit A attached hereto.

IN THE SPECIFICATION

On page 2, lines 5 and 6, please delete the words
"each of which are filed on this same day," and after the word 'following', please insert the words
-- patent applications –
On page 2, line 6, after the word 'each' and before the word 'incorporated', please insert the words
-- of which is hereby --
On page 2, line 6, please delete the word "each" preceding the word 'assigned'.
On page 2, line 8, please delete the words
"United States patent application entitled" and replace with the words
-- U.S. Patent Appln. Ser. No. 09/017,198 filed February 2, 1998 for --
On page 2, line 9, please replace the word "of" with the word -- to --
On page 2, line 9, please delete the words "(Our File: P-7521) "
On page 2, line 10, please delete the words
"United States patent application entitled" and replace with the words
-- U.S. Patent Appln. Ser. No. 09/017,195 filed February 2, 1998 for --
On page 2, line 11, please replace the word "of" with the word -- to --
On page 2, lines 11 and 12, please delete the words "(Our File: P-7354 (including P-7329))"
On page 2, line 13, please delete the words
"United States patent application entitled" and replace with the words
-- U.S. Patent Appln. Ser. No. 09/017,196 filed February 2, 1998 for --
On page 2, line 14, please replace the word "of" with the word -- to --
On page 2, line 15, please delete the words "(Our File: P-7356)".

On page 6, after line 14 please insert the following paragraph:
-- FIG. 10 is a flow chart depicting steps employed in a self-test feature according to one embodiment of the present invention. --

IN THE CLAIMS

Please cancel claims 1-23 in the original application, and add new claims 24 through 31 as set forth below:

24. A flow regulator, comprising:
a membrane having at least one hole;
a bottom layer; and
a fluid pathway;
the membrane being positioned above the bottom layer, the fluid pathway being defined from above the membrane through the hole and along the bottom layer on the side facing the membrane, wherein flow through the hole causes the membrane to deflect and engage against at least one portion of the bottom layer thereby impeding the fluid pathway.

25. A flow regulator according to claim 24, wherein the side of the bottom layer facing the membrane further comprises at least one channel which constitutes a part of the fluid pathway, the first end of the channel being in connection with an outlet port, wherein flow through the hole causes the membrane to deflect and engage against at least one portion of the bottom layer thereby forcing the fluid in this portion to flow only in the channel.

26. A flow regulator according to claim 25, wherein the shape and length of the channel are so designed that an increase of pressure generates an increase of the contact area between the membrane and the bottom layer, thereby defining an additional segment to the channel where fluid is confined, said configuration allowing a proper adjustment of the flow versus pressure characteristics.

27. A flow regulator according to claim 26, wherein the

section of the channel is constant.

28. A flow regulator according to claim 26, wherein the shape and length of the channel are so designed that the fluid resistance is proportional to the pressure, implying thereby a flow rate independent of the pressure.

29. A flow regulator according to claim 27 or 28, wherein the channel is a spiral shaped groove.

30. A flow regulator according to any of claims 24 to 29, wherein the membrane further includes means for sensing the deflection of the membrane.

31. A flow regulator according to any of claims 24 to 30, wherein the fluid pathway is obstructed when the membrane has reached a predetermined degree of deflection.

REMARKS

Applicant submits the claims, as now presented, are all in a condition for allowance. Passage of the case to issue is respectfully required. The Examiner is encouraged to call the undersigned on (31) 43 356 6845 to discuss any matters which may aid in passing the case to issue.

Respectfully submitted,

Markus Haller et al.

By their attorney,

11-10-00

Date

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PATENT
Our File: P-7322
Includes P-7353

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

TITLE: IMPLANTABLE DRUG INFUSION DEVICE HAVING A FLOW REGULATOR

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IMPLANTABLE DRUG INFUSION DEVICE HAVING A FLOW REGULATOR

RELATED APPLICATIONS

This application is related to one or more of the following each of which are filed on this same day, each incorporated herein by reference and each assigned to the assignee of the present application:

- United States patent application entitled "System For Locating Implantable Medical Device" of Markus Haller and Koen Weijand (Our File: P-7521);

- United States patent application entitled "Implantable Drug Infusion Device Having A Safety Valve" of Markus Haller and Koen Weijand (Our File: P-7354 (including P-7329)); and

- United States patent application entitled "Implantable Drug Infusion Device Having An Improved Valve" of Markus Haller, T. S. J. Lammerink and Niels Olij (Our File: P-7356).

FIELD OF THE INVENTION

The present invention relates to the field of implantable drug infusion devices and more particularly to an implantable drug infusion device having a flow regulator.

BACKGROUND OF THE INVENTION

Implantable drug infusion devices are used to provide patients with a constant or programmable long term dosage or infusion of a drug or any other therapeutic agent. Essentially such device may be categorized as either active or passive.

Active drug or programmable infusion devices feature a pump or a metering system to deliver the drug into the patient's system. An example of such an active drug infusion device currently available is the Medtronic SynchroMed™ programmable pump. Such pumps typically include a drug reservoir, a peristaltic pump to pump out the drug from the reservoir, and a catheter port to transport the pumped out drug from the reservoir via the pump to a patient's anatomy. Such devices also typically include a battery to power the pump as well as an electronic module to control the flow rate of the pump. The Medtronic SynchroMed™ pump further includes an antenna to permit the remote programming of the pump. Needless to say, in view of these various components, the cost as well as the size of active drug infusion devices is greater than desired.

Passive drug infusion devices, in contrast, do not feature a pump, but rather rely upon a pressurized drug reservoir to deliver the drug. Thus such devices tend to be both smaller as well as cheaper as compared to active devices. An example of such a device includes the Medtronic IsoMed™. This device delivers the drug into the patient through the force provided by a pressurized reservoir. In particular, this reservoir is pressurized with a drug to between 20 to 40 psi (1.3 to 2.5 bar) and is used to deliver the drug into the patient's system. Typically the flow path of the drug

from the reservoir to the patient includes a flow restrictor, which permits a constant flow rate. The flow rate, however, is only constant, if the pressure difference between reservoir and patient does not change. Factors that could impact this pressure difference include temperature, pressure-volume dependence of reservoir and altitude, among others. The selected pressure for the reservoir is thus typically quite high, so that absolute pressure changes only cause small and acceptable errors in flow rate. This also requires, however, the drug to be injected into the reservoir using still higher pressure. This is often a very difficult to achieve using a hand operated syringe.

In addition such devices present challenges to accurately deliver a precise dosage of drug to the patient. As the amount of drug is removed from the reservoir, the pressure in the reservoir drops. This, in turn, affects the flow rate such that only over a limited pressure range will the flow rate be constant. Still further, because the ambient pressure changes in which the patient exists (due to weather or altitude for example) the resistance to drug infusion likewise changes, further affecting the flow rate. Temperature will also have a similar impact.

Thus there is a need for a drug infusion system which will permit the drug flow rate to be independent of reservoir pressure within a given pressure range.

SUMMARY OF THE INVENTION

The present invention provides an implantable drug infusion device

which features an improved flow regulator which permits the flow rate to be independent of reservoir pressure within a given pressure range. The flow regulator features a membrane having a hole, the membrane itself positioned above a bottom layer such that sufficient deflection of the membrane causes the membrane to engage against the bottom layer. As liquid flows through the hole a force is applied to the membrane, resulting in a deflection of the membrane which, in turn, impedes the flow path. In a further embodiment the bottom layer features a variable flow channel such that upon membrane deflection flow may only proceed through the hole and through the flow channel. By tailoring the shape and length of the variable flow channel the flow characteristics of the regulator versus pressure may be adjusted. In a further embodiment the flow regulator also features a flow sensor integrated therewith. This integrated sensor provides a measurement of flow and may be coupled to the flow regulator to provide feedback thereto.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of an implantable drug infusion device according to the present invention.

FIG. 2 is a side view of a flow regulator according to the present invention in which the system pressure is low and the regulator membrane is not deflected.

FIG. 3 is a side view of a flow regulator according to the present invention in which the system pressure is high and the membrane is deflected.

FIG. 4 is a side view of a further embodiment of a flow regulator.

FIG. 5A is a top view of the variable flow restrictor channel used in the embodiment depicted in FIG. 4 of the present invention.

FIG. 5B is a sectional view of the variable flow restrictor shown in FIG. 5A.

FIG. 5C is a sectional view of an alternative variable flow restrictor channel.

FIG. 6 depicts the flow versus pressure for one embodiment of the present invention showing, in particular, the linear flow between the two pressures which may be permitted using this present invention.

FIG. 7 is a block diagram of an implantable drug infusion device which features an integrated self-test mechanism on the flow regulator.

FIG. 8 is a side view of a flow regulator which features an integrated self-test mechanism on the flow regulator.

FIG. 9 depicts the change in resistance of the piezo-resistors used in the flow sensors versus reservoir pressure.

The FIGS. are not necessarily to scale.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of an implantable drug infusion device and in particular of a passive system to deliver drugs and other therapeutic agents. As seen, such a system 1 comprises a reservoir 2, flow regulator 3 and outlet catheter 4. The reservoir is a pressurizable reservoir to hold drugs and other

therapeutic agents. Reservoir may be of a standard design, such as that used in the above mentioned Medtronic IsoMed™ implantable drug infusion system. Flow regulator 3 is coupled to the reservoir and the outlet catheter. Flow regulator controls the flow of material which may be transmitted from the reservoir to the outlet catheter and in particular permits the flow rate to be independent of reservoir pressure within a given pressure range. System may be refilled through injection port 5 through the use of a needle 6 as is well known. Surrounding all components of the implantable pump other than the outlet catheter is a hermetic closure 13 as is well known in the art.

FIG. 2 is a side view of a flow regulator according to the present invention. In this view the reservoir pressure is low. As seen, flow regulator comprises a membrane 21, 22 cantilevered from shoulders 23 and 24 respectively. In the preferred embodiment membrane is circular, although other shapes may also be used, e.g. rectangular.

Center of the membrane features flow lumen 25. The membrane is further disposed above a substrate 30 such that cavity 31 is defined. Substrate 30, in turn, has an outflow tract 32 coupled to cavity 31. Thus, unless activated by pressure, the membrane remains in the position as shown and fluid flows through flow lumen 25 into cavity 31 and thereafter through outflow tract 32. Outflow tract is coupled, in turn, to outlet catheter (although not shown in this view). Outlet catheter may be of any model desired and suited to the patient's requirements.

Depending on the amount of pressure exerted by the fluid, the membrane may be either in the position shown or deflected any amount as permitted by substrate 30. In the preferred embodiment shoulders and membrane are silicon and substrate is Pyrex™glass, although other materials may also be used such as titanium or tantalum. Moreover, the areas of substrate and membranes in contact with any drug or fluid are further preferably coated with diamond or diamond-like carbon so as to inhibit any interactions between the drug or fluid and the materials. Such coatings may be selected according to the particular drug or fluid to be infused.

FIG. 3 is a side view of a flow regulator according to the present invention in which the system pressure is high. As seen in this embodiment, the pressure of the fluid causes the membrane to be deflected and strike against substrate 30. In such a manner the fluid pathway (flow lumen 25 into cavity 31 and thereafter through outflow tract 32) is blocked by the membrane itself and all fluid flow is thus stopped.

FIG. 4 is an additional embodiment of the present invention and, in particular, the preferred embodiment of flow regulator which features a variable flow restrictor channel 33. As seen in this embodiment, flow regulator features a variable flow restrictor channel which provides a pathway through which flow may continue even though the membrane is disposed against a surface in substrate 30. In particular, flow proceeds through lumen 25 into the variable flow restrictor channel 33 to the outlet 32. Because membrane strikes the top of substrate all flow is forced to go to the "beginning" of the variable flow restrictor channel. As more pressure is applied

to the membrane by the fluid, the membrane is deflected to a greater degree, a greater contact area is made between the membrane and the substrate, and the fluid is forced to flow through a longer pathway through the variable flow restrictor channel. In the preferred embodiment the length of the flow channel is directly proportional to the flow resistance. The increase in contact area due to pressure proportionally lengthens the distance in which the fluid flows exclusively within the flow channel. Thus the flow through the restrictor channel is directly proportional to the pressure applied to the fluid within that channel. This capability thus provides this embodiment with the ability to directly compensate pressure inaccuracies as well as pressure variations within any of the system components (upstream of the flow sensor) such as the reservoir, when such pressure anomalies are with the (upstream of the flow sensor) specified pressure region. Ultimately, this design permits the flow rate to be independent of reservoir pressure within a given pressure range.

FIG. 5A is a top view of a variable flow restrictor channel used in the preferred embodiment. As seen in this embodiment, restrictor channel is essentially spiral shaped according to the following equation:

$$x = \frac{a \cdot \cos t}{t} \quad \text{and} \quad y = \frac{a \cdot \sin t}{t} \quad \text{for } -\infty < t < 0 \text{ and } 0 < t < \infty$$

where "a" is 1 in the preferred embodiment, although any value between approximately 0.1 to 100 may also be chosen

FIG. 5B is a sectional view of the flow restrictor channel of FIG. 5A taken along the line 5B-5B. As seen in this embodiment, the restrictor channel is

essentially square in shape and has a depth roughly equal to the width. Of course, other cross sectional shapes of restrictor channel may also be used, such as circular, as seen in FIG. 5C or other shapes, triangular, etc. What is important for the flow characteristics of the regulator, however, is the cross sectional area of the channel. In the preferred embodiment the channel has a width of 15 μm and depth of 10 μm which permits a essentially constant flow rate of 500 μl over a pressure range of between approximately 2 to 8 psi above ambient pressure. Moreover, although the cross sectional area and shape of the restrictor channel is constant in the preferred embodiment, either the shape or area or both may be varied along the various portions in order to provide other flow characteristics besides those of the preferred embodiment.

FIG. 6 is a graph showing the flow rate versus pressure of the preferred embodiment. As seen, due to the usage of the deflected leaflets in conjunction with the variable flow restrictor channel the flow rate may be caused to be constant over a pressure range. In this chart P1 is 2 psi, P2 is 8 psi and F1 is 500 ml.

FIG. 7 is a block diagram of an alternative embodiment of the present invention. As seen, such a system 1 comprises a reservoir 2, flow regulator/flow sensor 7, electronic controls 10, battery 11, telemetry assembly 12 and outlet catheter 4. Flow regulator/flow sensor 7 is coupled to the reservoir across safety valve 16 and further coupled to the outlet catheter across pump 17. Flow

regulator/flow sensor regulates the flow of material which may be transmitted from the reservoir to the outlet catheter by pump in a manner to the flow regulator already described above, i.e. it regulates flow such that flow rate is independent of reservoir pressure within a given pressure range. Moreover, in this embodiment, the flow regulator also functions as a flow sensor to permit the flow rate to be sensed such that the device can track how much drug is delivered. Further, this component also permits the device to test itself so as to check and monitor the actual flow rate. As already described above, the system may be refilled through injection port 5 through the use of a needle 6 as is well known. Surrounding all components of the implantable pump other than the outlet catheter is a hermetic closure 13 as is well known in the art. Electronic controls 10, battery 11, telemetry assembly 12 and pump 17 are all constructed in any manner well known in the art. Electronic controls are powered by battery 11 and may receive remote operation instructions via telemetry assembly 12, as is well known in the art. Safety valve is preferably of a design as shown in the co-pending application of Haller et al. "Implantable Infusion Device Having Safety Valve" (P-7356) filed this same day and incorporated herein by reference.

FIG. 8 is a side view of a flow regulator/flow sensor used in the system of FIG. 7 As seen, this embodiment is essentially the same as that shown in FIG. 4. That is, flow regulator comprises membrane 21 cantilevered from shoulders 23 and 24 respectively disposed above a variable flow restrictor channel within

substrate 30. As already discussed above, channel provides a pathway through which flow may continue even though the membrane is disposed against the surface of substrate 30. In the present embodiment, the flow regulator/flow sensor further features one or more piezo-resistive elements 40, 41 integral with the membrane such that deformation or bending of the leaflets is detected by the elements. Such elements are coupled to the electronic controls, which process the signals and extract information as to element deformation and thus flow through the valve. Although piezo-resistive elements are used, other types of elements may also be used, such as capacitive or inductive.

FIG. 9 is a graph showing the change in resistance to flow versus pressure of the preferred embodiment. As seen, due to the usage of the deflected membrane in conjunction with the variable flow restrictor channel the change is resistance to flow increases in proportion to the pressure.

FIG. 10 is a flow chart depicting the steps used of a self-test feature made possible through the one or more piezo-resistive elements 40, 41 integral with the membrane. In particular this feature is used to quantify membrane deflection. This is important because, the membranes may, over time, take a set, that is exhibit a permanent deflection. Thus the self test permits the membrane position to be precisely measured. Such information may be then used to assess device operation, e.g. the actual flow rate of fluid through the regulator. amount of refill reservoir required by the or device malfunction. Typically this self test procedure

is performed at device implant or follow-up by the physician.

As seen in FIG. 10 at 10-1 a first amount of energy is apply across one or more piezo-resistive elements 40, 41. Next at 10-2 a parameter indicated through the first amount of energy is sensed. Such parameters may include resistance, impedance or capacitance, for example. Because in the preferred embodiment the elements are piezo-resistive, then the parameter preferably sensed would be the electrical resistance in the elements. The exact type of parameter is not crucial to the self test feature, nor is it whether the elements are piezo resistive or piezo capacitive, etc. Next at 10-3 a second amount of energy is apply across one or more piezo-resistive elements 40, 41 while a know pressure is generated in the reservoir. Next at 10-4 a second parameter indicated through the second amount of energy is sensed. At 10-5 the sensed second parameter is calibrated against the preceding known pressure and the quantity of membrane deflection is determined. This, in turn, indicates flow. At 10-6 runs a self diagnosis to determines, among other things, whether the sensed flow is within a predetermined range, if not, then the device closes a valve and shuts down. Otherwise the device uses the new data to correct the sensed deflection against the known pressure and create a new baseline for future measurements.

Although a specific embodiment of the invention has been disclosed, this is done for purposes of illustration and is not intended to be limiting with regard to

the scope of the invention. It is contemplated various substitutions, alterations and/or modifications may be made to the disclosed embodiment without departing from the spirit and scope of the invention. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

What is claimed is:

1. An implantable drug infusion device comprising:

a hermetic enclosure;

a fluid reservoir positioned within the hermetic enclosure, the fluid reservoir having means for maintaining the fluid therein within a first pressure and a second pressure; the fluid reservoir having an fluid outlet port;

means for delivering a fluid into a patient's body; and

a flow regulator coupled to the fluid outlet port, the flow regulator coupled to the means for delivering a fluid into a patient's body the flow regulator having a fluid pathway between the fluid outlet port and the means for delivering a fluid into a patient's body, the flow regulator further having means for permitting fluid to flow within the fluid pathway when the fluid in the reservoir is at a pressure which is more than the first pressure and less than the second pressure.

2. An implantable drug infusion device according to claim 1 wherein the flow regulator comprises a membrane, a shoulder and a bottom layer, the membrane having a hole, whereby the fluid pathway is defined from above the membrane, through the hole and along the bottom layer, whereby flow through the hole causes the membrane to deflect and engage the bottom layer thereby impeding the fluid pathway.

3. An implantable drug infusion device according to claim 2 further comprising a membrane deflected by fluid flow within the fluid pathway.

3. An implantable drug infusion device according to claim 2 further comprising the membrane cantilevered from the shoulder over the bottom layer,

4. An implantable drug infusion device according to claim 3 further comprising means for determining any deflection in the membrane.

5. An implantable drug infusion device according to claim 4 wherein the membrane further includes means for sensing the deflection of the membrane.

6. An implantable drug infusion device according to claim 5 means for calibrating the sensed deflection of the membrane with the rate of fluid flow through the fluid pathway.

7. An implantable drug infusion device according to claim 1 wherein the flow regulator comprises a membrane, a shoulder and a bottom layer, the bottom layer having a channel therein, the membrane cantilevered from the shoulder over the bottom layer, the membrane having a hole, whereby the fluid pathway is defined

from above the membrane, through the hole and along the bottom layer, whereby flow through the hole causes the membrane to deflect and engage the bottom layer thereby permitting the fluid pathway to only exist within the channel.

8 . An implantable drug infusion device according to claim 1 further comprising means for varying the length of the flow channel.

9. An implantable drug infusion device comprising:

a hermetic enclosure;

a fluid reservoir positioned within the hermetic enclosure, the fluid reservoir having an fluid outlet port;

means for delivering a fluid into a patient's body; and

a flow regulator coupled to the fluid outlet port, the flow regulator coupled to the means for delivering a fluid into a patient's body the flow regulator having a fluid pathway between the fluid outlet port and the means for delivering a fluid into a patient's body, the flow regulator having a membrane, a shoulder and a bottom layer, the membrane cantilevered from the shoulder over the bottom layer, the membrane having a hole, whereby the fluid pathway is defined from above the membrane, through the hole and along the bottom layer, whereby flow through the hole causes the membrane to deflect and engage the bottom layer thereby impeding the fluid pathway.

10.. An implantable drug infusion device according to claim 9 wherein the bottom layer having a channel therein, whereby flow through the hole causes the membrane to deflect and engage the bottom layer thereby permitting the fluid pathway to only exist within the channel.

11. An implantable drug infusion device according to claim 10 wherein the membrane further includes means for sensing the deflection of the membrane.

12. An implantable drug infusion device according to claim 11 means for calibrating the sensed deflection of the membrane with the rate of fluid flow through the fluid pathway.

13. An implantable drug infusion device according to claim 9 wherein the flow regulator comprises a membrane, a shoulder and a bottom layer, the bottom layer having a channel therein, the membrane having a hole, whereby the fluid pathway is defined from above the membrane, through the hole and along the bottom layer, whereby flow through the hole causes the membrane to deflect and engage the bottom layer thereby permitting the fluid pathway to only exist within the channel.

14. An implantable drug infusion device according to claim 9 further comprising means for varying the length of the flow channel.

15. An implantable drug infusion device comprising:

a hermetic enclosure;

a fluid reservoir positioned within the hermetic enclosure, the fluid reservoir having means for maintaining the fluid therein within a first pressure and a second pressure; the fluid reservoir having an fluid outlet port;

means for delivering a fluid into a patient's body;

a flow regulator coupled to the fluid outlet port, the flow regulator coupled to the means for delivering a fluid into a patient's body the flow regulator having a fluid pathway between the fluid outlet port and the means for delivering a fluid into a patient's body, the flow regulator further having means for permitting fluid to flow within the fluid pathway when the fluid in the reservoir is at a pressure which is more than the first pressure and less than the second pressure; and

means for sensing the rate of fluid flow through the flow regulator:

16. An implantable drug infusion device according to claim 15 wherein the means for sensing the rate of fluid flow through the flow regulator:
comprises a membrane deflected by fluid flow within the fluid pathway.

17. An implantable drug infusion device according to claim 16 further comprising means for determining any deflection in the membrane.

18. An implantable drug infusion device according to claim 17 further comprising means for calibrating any deflection in the membrane against a predetermined fluid pressure in the reservoir.

19. An implantable drug infusion device comprising

a hermetic enclosure;

a fluid reservoir positioned within the hermetic enclosure, the fluid reservoir having means for maintaining the fluid therein within a first pressure and a second pressure; the fluid reservoir having an fluid outlet port;

means for delivering a fluid into a patient's body;

a flow regulator coupled to the fluid outlet port, the flow regulator coupled to the means for delivering a fluid into a patient's body the flow regulator having a fluid pathway between the fluid outlet port and the means for delivering a fluid into a patient's body, the flow regulator further having means for permitting fluid to flow within the fluid pathway when the fluid in the reservoir is at a pressure which is more than the first pressure and less than the second pressure; and

means for sensing the flow through the flow regulator.

20. An implantable drug infusion device according to claim 19 further comprising means for calibrating the means for sensing the flow through the flow regulator.

21. An implantable drug infusion device according to claim 20 wherein the means for sensing comprise a deflectable membrane, the membrane have one or more elements indicating membrane deflection.

22. An implantable drug infusion device according to claim 21 further comprising

means apply a first amount of energy is applied across one or more elements;

means for sensing a parameter indicated through the first amount of energy applied across one or more elements

means for generating a known pressure in the reservoir

means for applying a second amount of energy across one or more elements while a know pressure is generated in the reservoir

means for sensing a second parameter indicated through the second amount of energy;

means for calibrating sensed second parameter against the preceding known pressure and determine quantity of membrane deflection

23. An implantable drug infusion device according to claim 19 further comprising means for determining any deflection in the membrane caused by a pressure to the

fluid in the reservoir and adjusting the determined deflection to compensate for any changes in the membrane shape to thereby provide a measure of fluid flow through the flow regulator.

ABSTRACT

An implantable drug infusion device which features an improved flow regulator which permits the flow rate to be independent of reservoir pressure within a given pressure range. The flow regulator features a membrane having a hole, the membrane itself positioned above a bottom layer such that sufficient deflection of the membrane causes the membrane to engage against the bottom layer. As liquid flows through the hole a drag force is applied to the edge of the hole resulting in a deflection of the membrane. Once contact is made between the membrane and the bottom layer, then flow reduced. In a further embodiment the bottom layer features a variable flow channel such that upon membrane deflection flow may only proceed through the hole and through the flow channel. By tailoring the shape and length of the variable flow channel the flow characteristics of the regulator versus pressure may be adjusted. In a further embodiment the flow regulator also features a flow sensor integrated therewith. This integrated sensor provides a measurement of flow and may be coupled to the flow regulator to provide feedback thereto.

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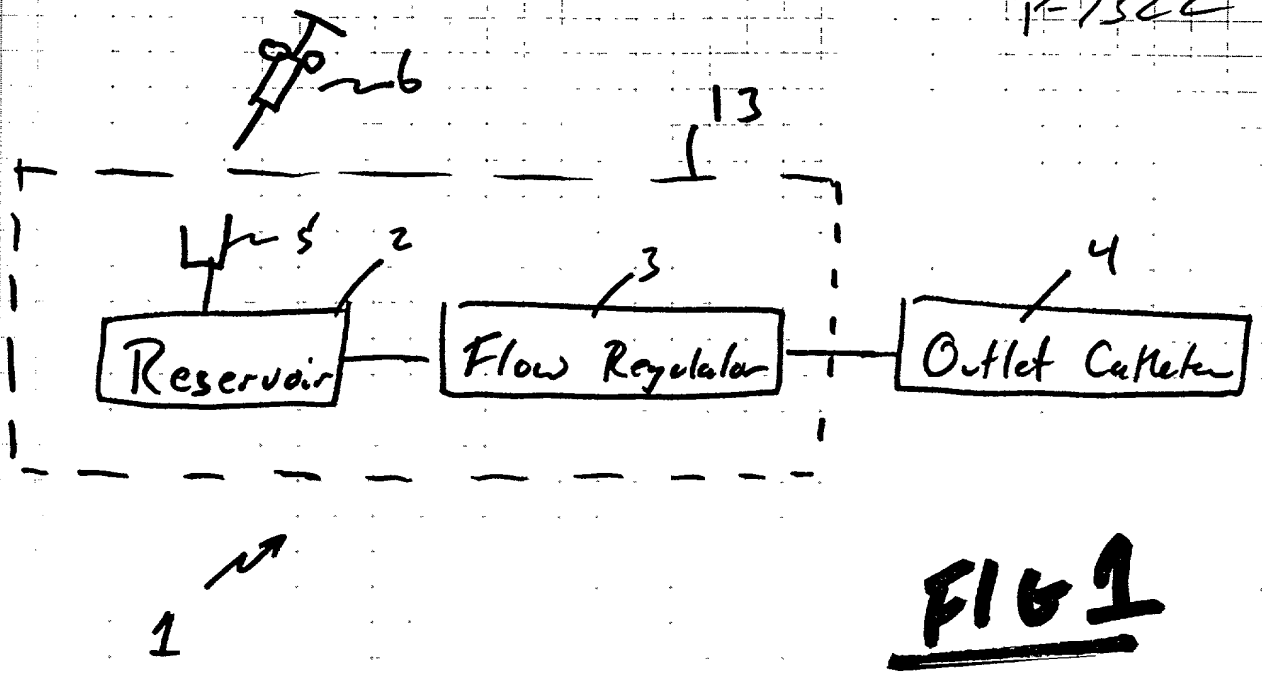

FIG 1

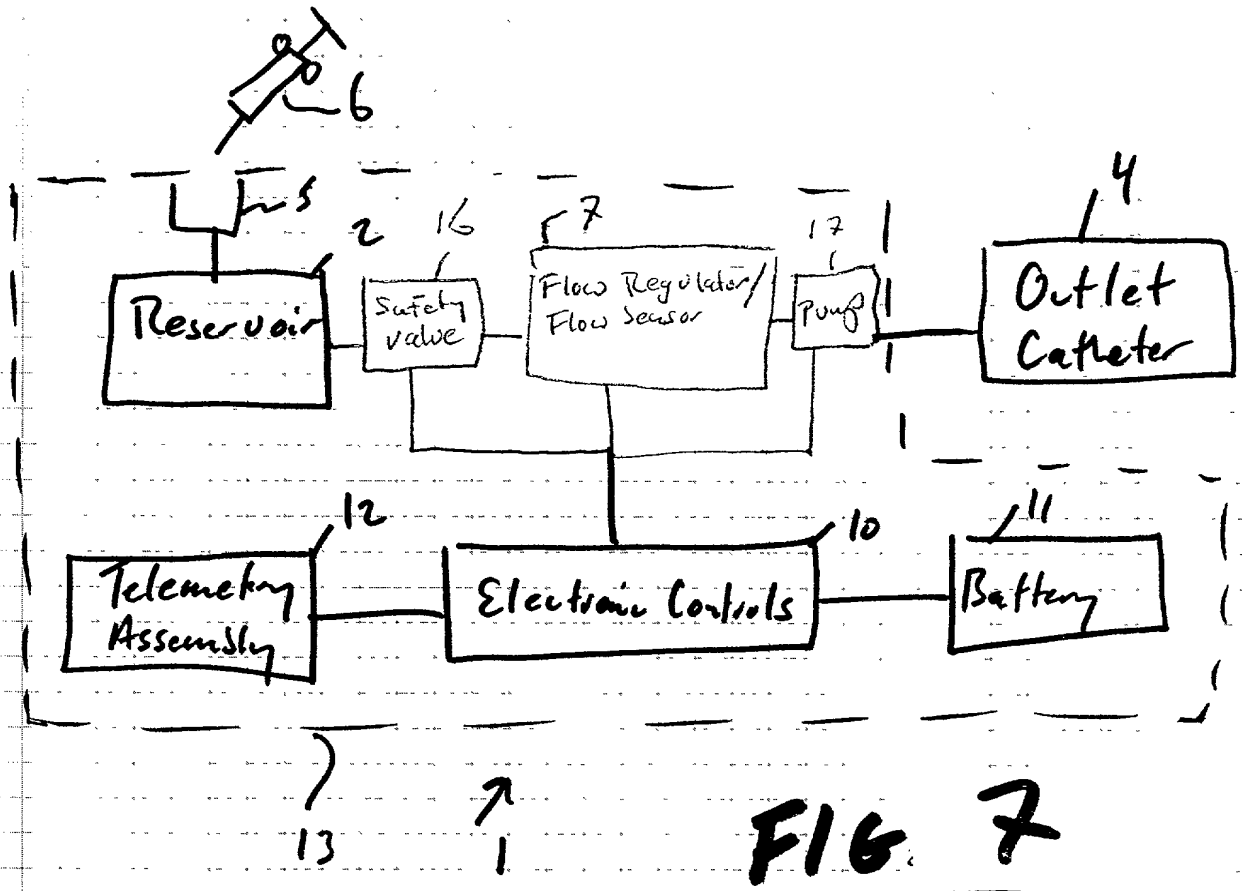

FIG 7

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FIG 2

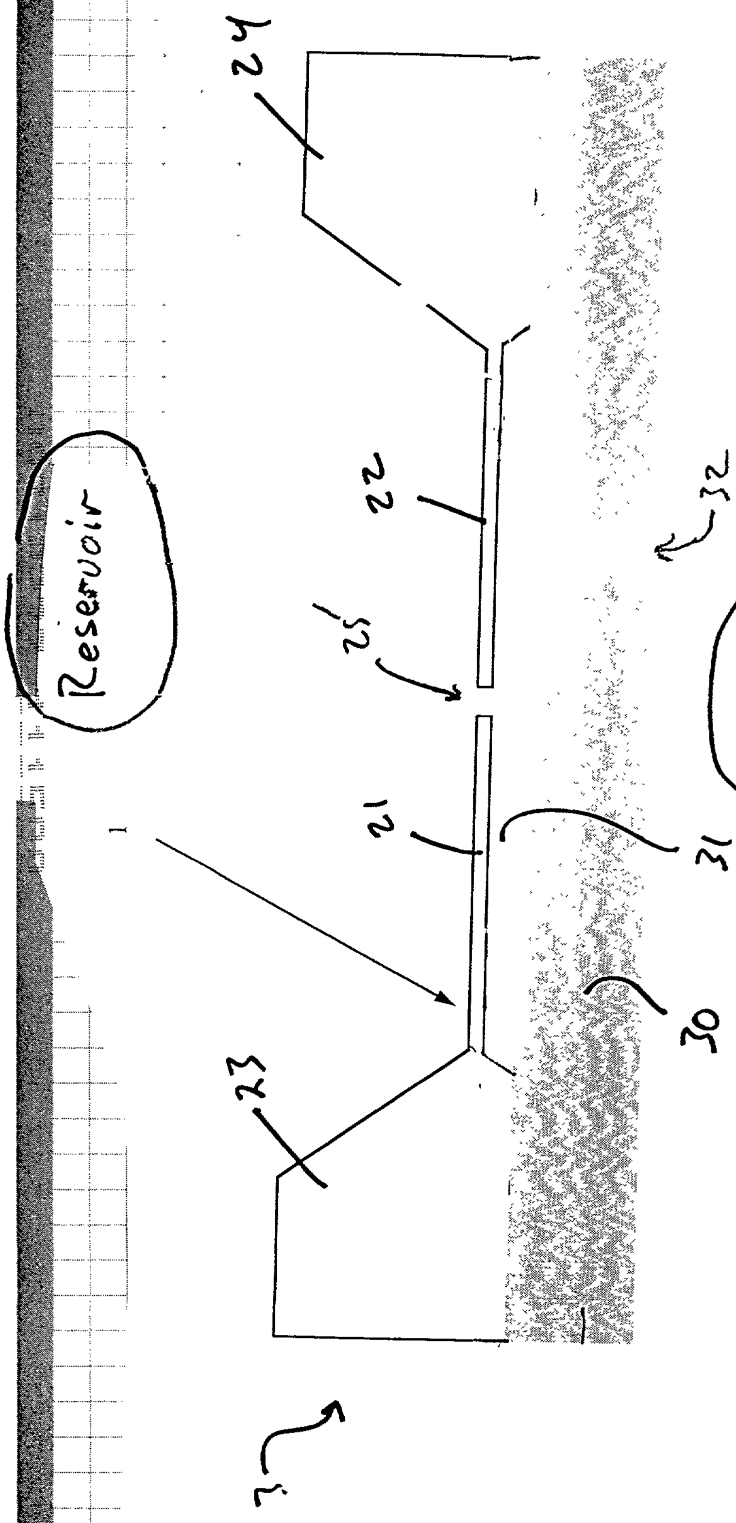
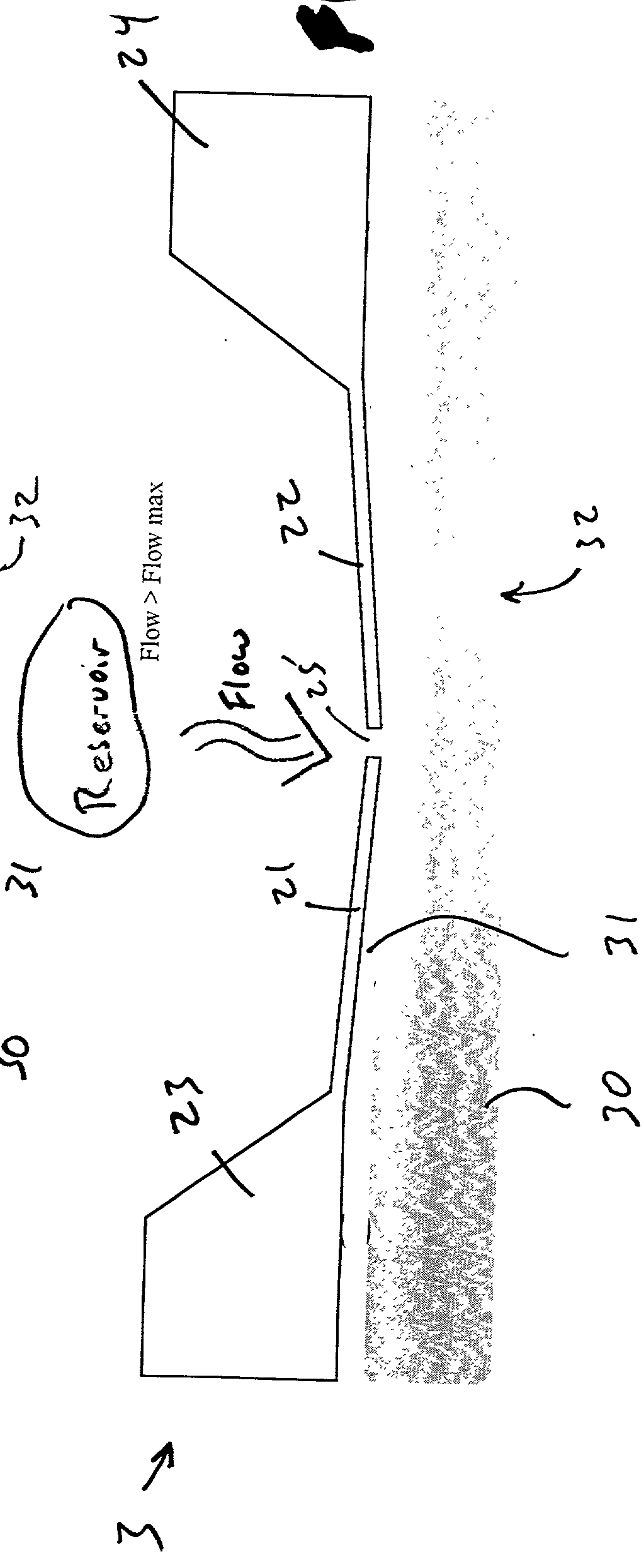
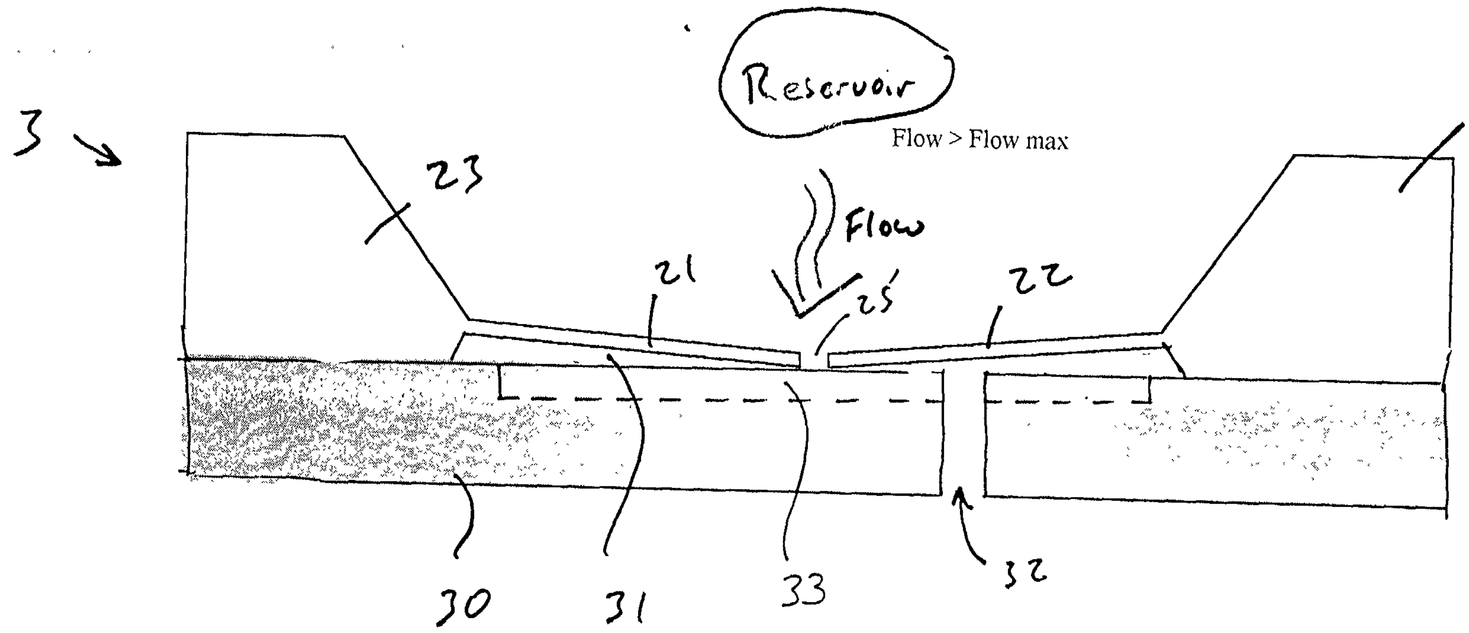


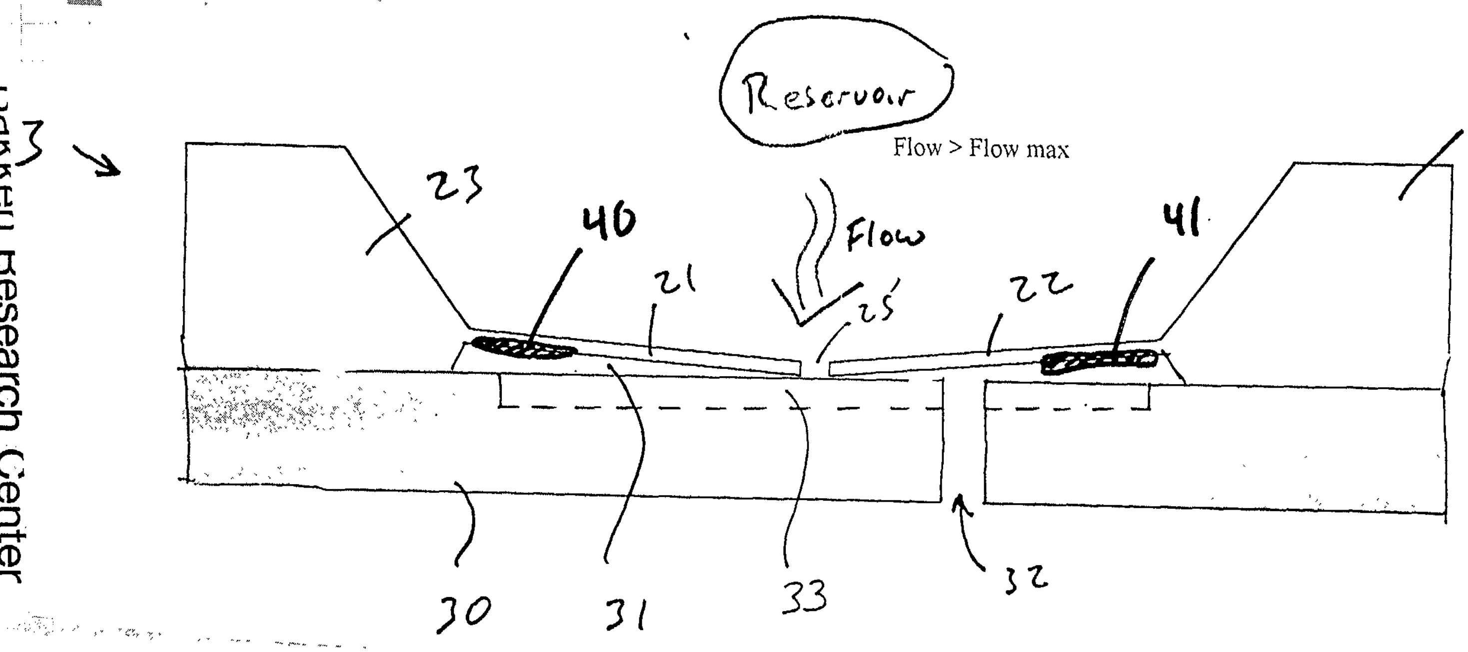
FIG 3





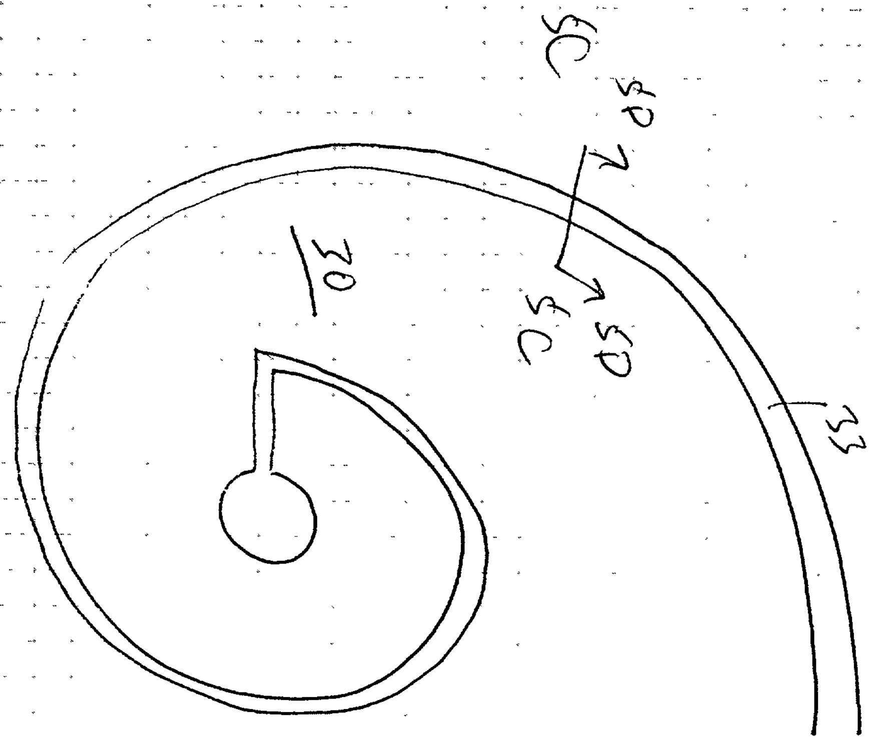
Reservoir
Flow > Flow max
Flow
3
23
24
21
25
22
30
31
33
32

FIG 4



Reservoir
Flow > Flow max
Flow
3
23
24
40
41
21
25
22
30
31
33
32

FIG 8



5A

FIG 5C

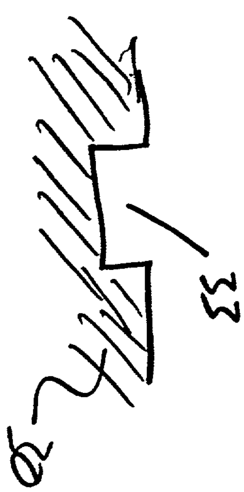


FIG 5B

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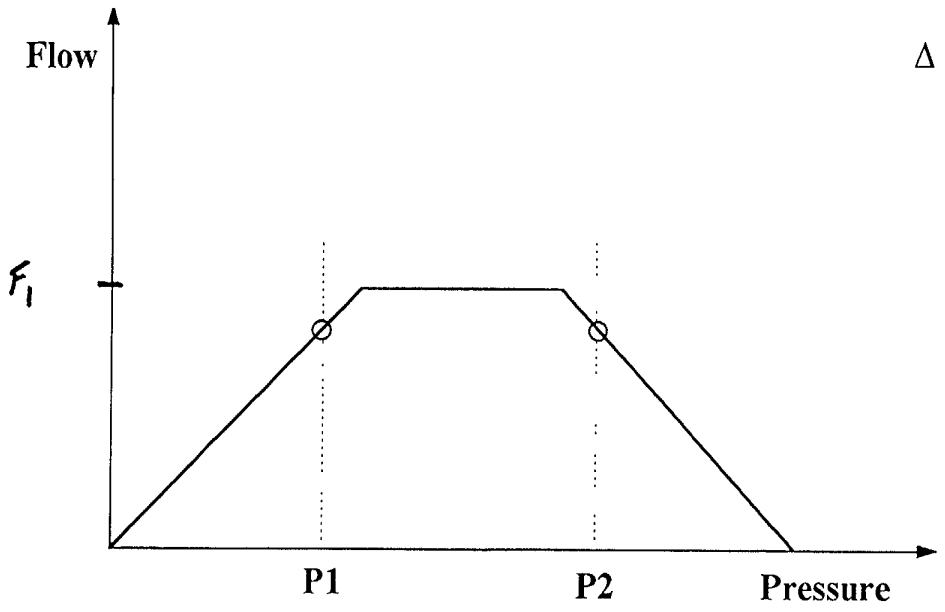

FIG 6

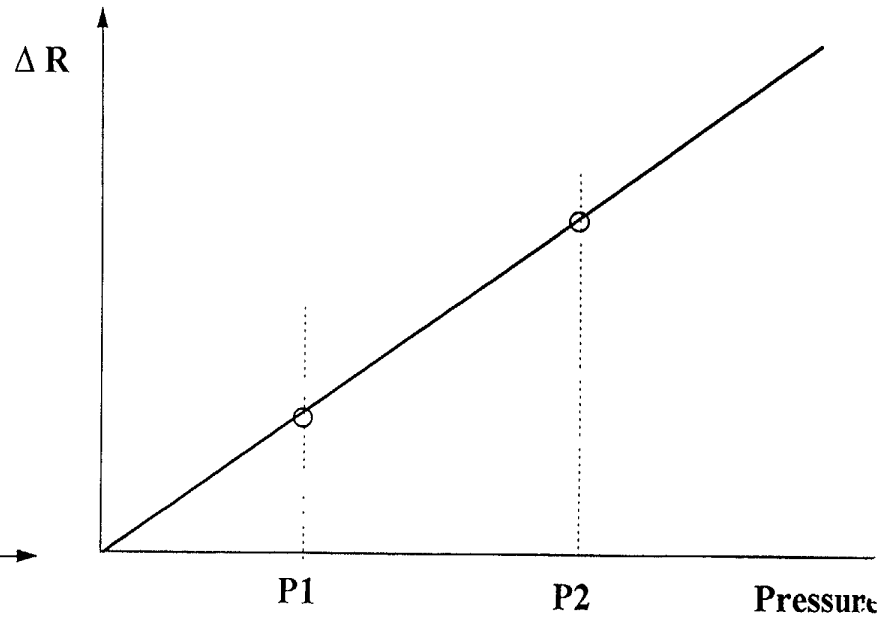

FIG 9

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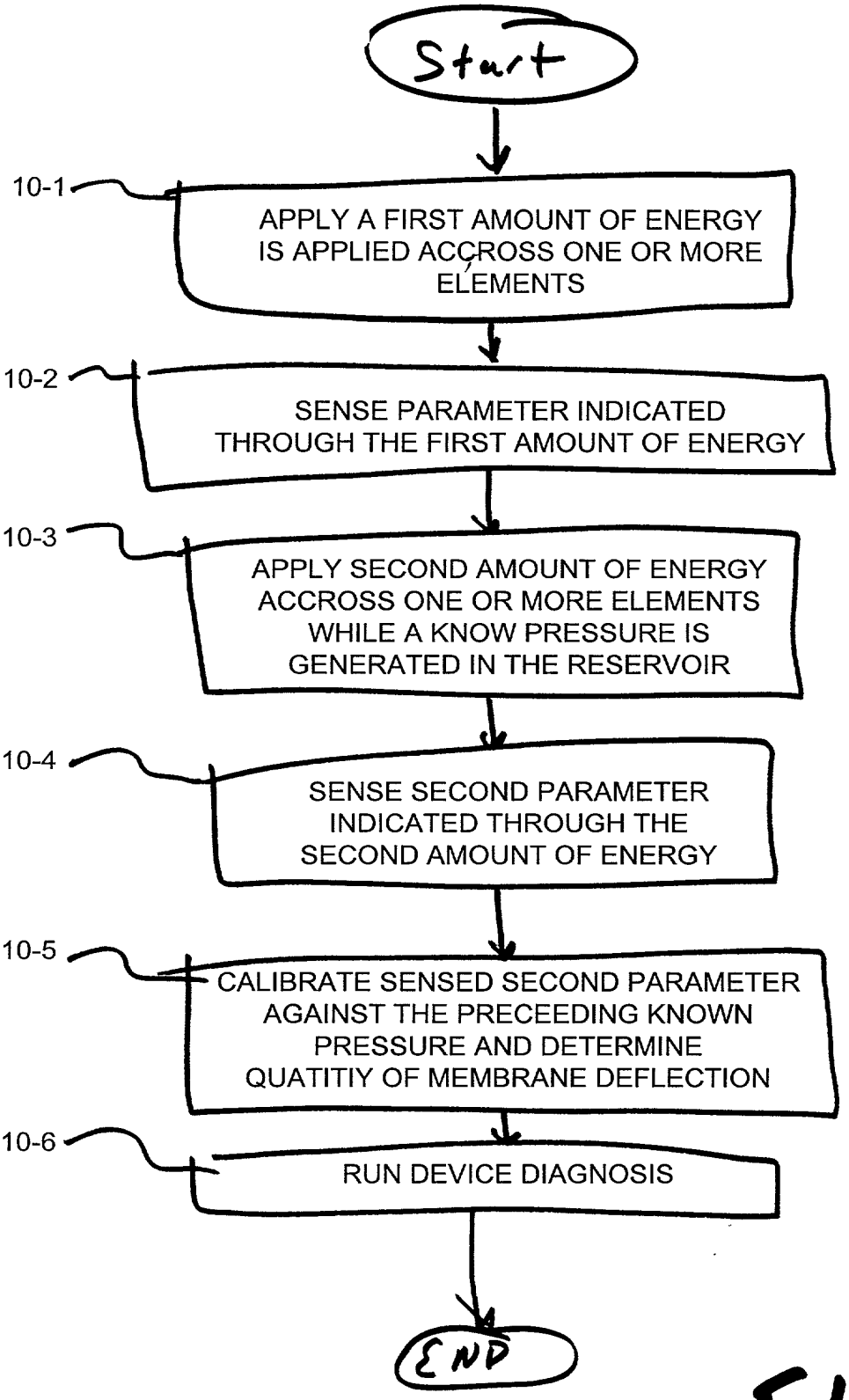
Start
10-1
APPLY A FIRST AMOUNT OF ENERGY IS APPLIED ACCROSS ONE OR MORE ELEMENTS
10-2
SENSE PARAMETER INDICATED THROUGH THE FIRST AMOUNT OF ENERGY
10-3
APPLY SECOND AMOUNT OF ENERGY ACCROSS ONE OR MORE ELEMENTS WHILE A KNOW PRESSURE IS GENERATED IN THE RESERVOIR
10-4
SENSE SECOND PARAMETER INDICATED THROUGH THE SECOND AMOUNT OF ENERGY
10-5
CALIBRATE SENSED SECOND PARAMETER AGAINST THE PRECEEDING KNOWN PRESSURE AND DETERMINE QUATITIY OF MEMBRANE DEFLECTION
10-6
RUN DEVICE DIAGNOSIS
END

FIG 10

ATTORNEY DOCKET: P-7322

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: IMPLANTABLE DRUG INFUSION DEVICE HAVING A FLOW REGULATOR.

The specification of which
a. ___ is attached hereto
b. X was filed on FEBRUARY 2, 1998 as application serial no. 09/017,194 and was amended on __ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. ___ filed ___ and as amended on __ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. x no such applications have been filed.
b. ___ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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SIGNATURE OF INVENTOR 203				DATE April 18 1998

__ Additional pages for fourth and subsequent inventors attached.

X This Declaration ends with this page.